



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130 and 131

[Docket No. FDA-2000-P-0126 (formerly Docket No. 2000P-0658)]

RIN 0910-AI40

Milk and Cream; Petition for an Administrative Stay of Action: Definitions and Standards of Identity for Yogurt, Lowfat Yogurt, and Nonfat Yogurt

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; notification of administrative stay.

SUMMARY: The Food and Drug Administration (FDA or we) is providing notice of a stay of the effectiveness of certain provisions of a final rule published in the *Federal Register* of June 11, 2021. The final rule amended the definition and standard of identity for yogurt and revoked the definitions and standards of identity for lowfat yogurt and nonfat yogurt. FDA is publishing this notification in response to objections timely filed in accordance with regulatory requirements.

DATES: FDA is administratively staying certain provisions in the final rule published on June 11, 2021 (86 FR 31117). FDA will publish a document in the *Federal Register* lifting the stay or taking further action as needed.

ADDRESSES: For access to the docket, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 11, 2021 (86 FR 31117), FDA issued a final rule (the 2021 final rule) amending the definition and standard of identity for yogurt ((§ 131.200) (21 CFR 131.200)) and revoking the definitions and standards of identity for lowfat yogurt (21 CFR 131.203) and nonfat yogurt (21 CFR 131.206). The 2021 final rule's effective date was July 12, 2021. Pursuant to section 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(e)), the 2021 final rule notified persons who would be adversely affected by the 2021 final rule that they could file objections, specifying with particularity the provisions of the 2021 final rule deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections.

The International Dairy Foods Association (IDFA) and Chobani timely filed objections and requests for a hearing with respect to several provisions in the 2021 final rule (see Objections and Request for Hearings submitted by Michael Dykes, DVM, President and Chief Executive Officer, International Dairy Foods Association, dated July 12, 2021, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA-2000-P-0126-0109) and Objection and Requests for Hearing submitted by Matthew Graziose, Ph.D., Director, Regulatory Affairs & Compliance, Chobani, dated July 12, 2021, to the Dockets Management Staff, Food and Drug Administration (Comment ID FDA-2000-P-0126-0108)). Section 701(e)(2) of the FD&C Act provides that, until final action is taken by the Secretary, the filing of objections operates to stay the effectiveness of those provisions to which the objections are made. We established the definition and standard of identity for yogurt in 1981 (1981 final rule) (46 FR 9924 at 9939, January 30, 1981). The 2021 final rule amended some provisions in the definition

and standard of identity and maintained others. Staying the effectiveness of these provisions results in the corresponding requirements in the 1981 final rule remaining in effect. This notice provides clarification on which provisions of the 2021 final rule have been stayed and which requirements of the 1981 final rule are in effect pending final action under section 701(e) of the FD&C Act.

II. Objections and Requests for Hearing

IDFA's objections were directed at several provisions in § 131.200(a) of the 2021 final rule. IDFA objected to the requirement in § 131.200(a) that yogurt, before the addition of bulky flavoring ingredients, has either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower. This provision of the 2021 final rule is stayed. FDA notes that the definition and standard of identity established in 1981 included a minimum titratable acidity requirement of 0.9 percent, but that provision was stayed by the filing of objections in 1981 (47 FR 41519 at 41523, September 21, 1982). Consequently, no minimum titratable acidity requirement or maximum pH requirement is in effect.

IDFA also objected to the provision that yogurt, before the addition of bulky flavoring ingredients, contains not less than 3.25 percent milkfat and the provision requiring pasteurized cream, if used as a basic dairy ingredient under § 131.200(b) or an optional dairy ingredient under § 131.200(c), to be added before culturing. These provisions of the 2021 final rule are stayed. However, a minimum milkfat of 3.25 percent before the addition of bulky flavors and the requirement that cream be included in the culturing process remain in effect under the definition and standard of identity established in the 1981 final rule.

Chobani objected to the exclusion of ultrafiltered milk from the basic dairy ingredients in § 131.200(b). This provision is stayed insofar as it prohibits the use of ultrafiltered milk. However, the provision in the 1981 final rule remains in effect with respect to the use of ultrafiltered milk. This means that ultrafiltered milk may not be used as a basic dairy ingredient in the manufacture of yogurt. Because we received no objections to the use of ultrafiltered milk

as an optional dairy ingredient under § 131.200(c) of the 2021 final rule, ultrafiltered milk may be used to increase the milk solids, not fat content, of the food above 8.25 percent, provided that the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of all protein present is not decreased as a result.

IDFA also objected to provisions in § 131.200(d) for other optional ingredients. These provisions included § 131.200(d)(2), which limits the use of sweeteners to nutritive carbohydrate sweeteners, and § 131.200(d)(8)(ii), which requires a minimum vitamin D content of 25 percent Daily Value (DV) per reference amount customarily consumed (RACC) if vitamin D is added. Both provisions in the 2021 final rule are stayed. Optional vitamin D addition has been permitted since 1982 at a level of 400 international units per quart (see 47 FR 41519 at 41520 and 41524); this limitation on vitamin D addition remains in effect. The prohibition on the use of sweeteners other than nutritive carbohydrate sweeteners remains in effect under the 1981 final rule's definition and standard of identity. Because we received no objections to permitting the use of all safe and suitable nutritive carbohydrate sweeteners, nutritive carbohydrate sweeteners are no longer limited to those listed under § 131.200(c)(2) in the 1981 final rule.

This notification does not constitute a determination that a hearing is justified on any objections or requests for hearing that have been filed (21 CFR 12.23). Until FDA makes such a determination and issues a notice under 21 CFR 12.28, 12.26, or 12.35, we intend to exercise enforcement discretion with respect to the following:

- Addition of vitamin D to yogurt under § 131.200 and lower fat yogurt products under § 130.10 (21 CFR 130.10) such that the food contains at least 10 percent DV per RACC, within limits of current good manufacturing practices.
- Use of nonnutritive sweeteners in yogurt under § 131.200 and lower fat yogurt products under § 130.10 that are not labeled with a statement of identity that includes an expressed nutrient content claim consistent with the use of nonnutritive sweeteners.

- Use of bulky flavor ingredients in lower fat yogurt products under § 130.10 that increase the total fat content above the level specified in § 101.62(b) (21 CFR 101.62(b)) for the expressed nutrient content claim in the statement of identity, provided that the level of milkfat in the product is consistent with the level specified in § 101.62(b) and the statement of identity also includes a descriptor of the bulky flavor ingredient (e.g., “lowfat yogurt with coconut”).

Under this enforcement discretion, we do not intend to take action with respect to yogurt and lower fat yogurt products that meet these criteria provided that the products otherwise conform to the definition and standard of identity under § 131.200 or § 130.10.

III. Provisions Stayed

Pursuant to section 701(e) of the FD&C Act, we hereby announce that the following provisions of the 2021 final rule are stayed by the objections filed:

1. The requirement in § 131.200(a) that yogurt, before the addition of bulky flavoring ingredients, has either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower.
2. The requirement in § 131.200(a) that yogurt, before the addition of bulky flavoring ingredients, contains not less than 3.25 percent milkfat.
3. The prohibition in § 131.200(a), (b), and (c) on adding pasteurized cream after culturing.
4. The exclusion of ultrafiltered milk from the basic dairy ingredients in § 131.200(b).
5. The limitation on the use of sweeteners in § 131.200(d)(2) to nutritive carbohydrate sweeteners.
6. The requirement in § 131.200(d)(8)(ii) that vitamin D, if added, must be present in such quantity that the food contains not less than 25 percent DV per RACC, within limits of current good manufacturing practices.

IV. Effective/Compliance Dates

This document hereby confirms the effective date of the 2021 final rule as July 12, 2021, and the compliance date as January 1, 2024, except with respect to the provisions in § 131.200(a), (b), (c), (d)(2), and (d)(8)(ii) stated above, which are stayed.

Dated: March 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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